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Traditional 510(k) Summary of Safety and Effectiveness

K092308

The Following Traditional 510(k) Summary of Safety and Effectiveness has been prepared pursuant to requirements for 510(k) summaries specified in 21 CFR § 807.92(a).

807.92(a)(1) - Submitter Details:

Submitter name:	Yair Penias –Quality and Regulatory Manager
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Contact Person:	Yair Penias –Quality and Regulatory Manager
Date:	March 11, 2009

807.92(a)(2) - Device Details:

Trade Name and Common Name:	PoleStar N30 - Magnetic Resonance Diagnostic Device, Also known as "PoleStar® N30 Surgical MRI System".
Classification:	21 CRF 892.1000 Magnetic Resonance Diagnostic Device.
Class:	II MRDD were reclassified by FDA from Class III to Class II effective July 28, 1998.
Product Code:	LNH – Magnetic Resonance Imaging System

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807.92(a)(3) – Predicate Devices:

The PoleStar N30 is comparable to:

Medical Device Name	Applicant Name	510(k) Number	Classification
PoleStar N-20	ODIN Technologies Ltd.	K032541	Class II device

Additional Substantial Equivalence Information is provided in the attached Substantial Equivalence Comparison Table.

807.92(a)(4) – Device Description:

The PoleStar N30 utilizes a permanent magnet to acquire 2D single-slice, multi slice, and 3d volume images. A wide variety of pulse sequences are provided to the operator, including spin echo, gradient echo, fast spin echo, and steady state free precession acquisitions. The PoleStar N30 is a widely open and compact Intraoperative MRI unit intended to be used in a typical pre-existing operating room. The PoleStar N30 can be moved within the room between procedures, from the operating table to its Magnet Storage Cabinet, thus allowing the operating room to be used for any type of surgery.

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807.92(a)(5) – Device Indication For Use:

The general purpose of the device as defined in 21 CFR 892.1000:

The PoleStar N30 is a Magnetic Resonance Diagnostic Device intended to produce transverse, sagittal, coronal, and oblique 2D and 3D images of sections of the head selected by the physician. The images produced by the PoleStar N30 reflect the spatial distribution of protons (Hydrogen Nuclei) exhibiting magnetic resonance. The NMR properties that determine the image appearance are proton density, spin-lattice relaxation time (T1), spin-spin relaxation time (T2) and T2*.

- Anatomical regions: sections of the head selected by the physician.
- Nuclei excited: H-1
- Diagnostic uses: T1, T2, T2* and density weighted imaging.

The PoleStar N30 is intended to be used intraoperatively in a standard operating room. When interpreted by trained physicians, the MR images provide information that can be useful in determining a diagnosis

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807.92(a)(6) – Substantial Equivalence Comparison Table:

Model / parameter	Odin *PoleStar* N-20 (K032541)	Medtronic Navigation *PoleStar* (Model: N30)
Clinical application	Extremities and selected sections of the head	sections of the head selected by the physician
Magnet type	Permanent	Permanent
Field strength	0.13T	0.13T
5 gauss fringe field (radial/axial, m)	2.2	2.2
Shimming	Passive, active	Passive, active
Gradient subsystem Strength mT/m Rise time to 10mT/m msec	 22 <1	 23.5 <0.15
Computer system - CPU: - Memory Cache size [MB] array processor - Memory size [GB] storage media	 Pentium 586 1 4xDSP C44 TI 40 magnetic disk, floppy disk	 P4 2.8GHZ 1 4xDSP C44 TI 160 magnetic disk, floppy disk
number of images stored	1,310,720	5,242,880
Imaging modes: - single - multislice - volume study - other	 Yes Yes Yes No	 Yes Yes Yes No
Reconstruction time: - single slice, sec - multislice, sec - volume sec	 <3/slice <3/slice <20/volume	 <2/slice <1/slice <16/volume
Cardiac gating	No	No

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Model / parameter	Odin *PoleStar* N-20 (K032541)	Medtronic Navigation *PoleStar* (Model: N30)
(ECG/peripheral)		
Respiratory gating	No	No
Angiography	Optional	Optional
Spectroscopy	No	No
Imaging; - pulse sequence	Spin Echo, Fast Spin Echo, Gradient Echo, 2D 3D	Spin Echo, Fast Spin Echo, Gradient Echo, 2D 3D
- repetition time, msec	10-5000 increments of 1	10-5000 increments of 1
- echo time, msec	3-150	2.5-150
- inversion time, msec	N/A	N/A
- slice thickness, mm	2-10	2-10
- scan orientation	Transverse, coronal, sagittal, oblique	Transverse, coronal, sagittal, oblique
- measuring matrix	64x64 to 256x256 steps of 1 in phase encoding	64x64 to 256x256 steps of 1 in phase encoding
- display matrix	1024x768	1024x768
- pixel intensity	0-4095	0-4095
Surface coils/Anatomical regions:		
- spine	No	No
- knee	Yes	No
- neck	No	No
- TMJ	No	No
- extremity	Yes	No
- head	Yes	Yes
- breast	No	No
- shoulder	No	No
- others	No	No
Bore diameter or WxH, cm	25.2x42	24.9 x42

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Model / parameter	Odin *PoleStar* N-20 (K032541)	Medtronic Navigation *PoleStar* (Model: N30)
Bore features	Open access to patient	Open access to patient
Cooling system type	Closed loop water cooling (Gradients only).	No
Cryogen use	No	No
Magnet weight, kg	400	330
HxWxD, cm	153x97x120	145x97x120
Filed Of View (FOV),cm	5-20	5-20
Dicom 3.0 interface	Yes	Yes
Power requirements: - line voltage, V - Kva - A/C, BTU/hr	 3x208 (3 phase) 15 <10000	 3x208 (3 phase) 8 <10000

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Yair Penias
Quality and Regulatory Manager
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ISRAEL

MAR 1 6 2010

Re: K092308
Trade/Device Name: PoleStar N-30
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: February 18, 2010
Received: February 22, 2010

Dear Mr. Penias:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): **K092308**

Device Name: **PoleStar N-30**

Indication For Use:

The PoleStar N-30 is a Magnetic Resonance Diagnostic Device intended to produce transverse, sagittal, coronal, and oblique 2D and 3D images of sections of the head selected by the physician. The images produced by the PoleStar N-30 reflect the spatial distribution of protons (Hydrogen Nuclei) exhibiting magnetic resonance.

The NMR properties that determine the image appearance are proton density, spin-lattice relaxation time (T1), spin-spin relaxation time (T2) and T2*.

Anatomical regions: **sections of the head selected by the physician.**

Nuclei excited: **H-1**

Diagnostic uses: **T1, T2, T2* and density weighted imaging.**

The PoleStar N-30 is intended to be used intraoperatively in a standard operating room. When interpreted by trained physicians, the MR images provide information that can be useful in determining a diagnosis.

(PLEASE DO NOT WRITE BELOW THE LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K092308

Attachment B

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